Complete Summary

GUIDELINE TITLE

Varicella vaccine update.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics. Committee on Infectious Diseases. Varicella vaccine update. Pediatrics 2000 Jan;105(1 Pt 1):136-41. [34 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Varicella zoster viral infections: varicella (chickenpox) and herpes zoster (shingles)

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Pediatrics

INTENDED USERS

Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide additional information on the varicella disease burden before the availability of varicella vaccine, potential barriers to immunization, efforts to increase the level of coverage, new safety data, and new recommendations for use of the varicella vaccine after exposure and in children with human immunodeficiency virus (HIV) infections

TARGET POPULATION

Children 12 months of age and older, including adolescents, without documentation of varicella immunization or infection

INTERVENTIONS AND PRACTICES CONSIDERED

Vaccination with live, attenuated varicella virus (VARIVAX™)

MAJOR OUTCOMES CONSIDERED

Morbidity and mortality associated with varicella virus infection

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The American Academy of Pediatrics reaffirms their recommendations for varicella vaccine use presented in the initial statement from the Committee on Infectious Diseases in 1995 (Recommendations for the use of live attenuated varicella vaccine. Pediatrics 1995;95:791-6).

Routine immunization of all susceptible children and adolescents without a contraindication is recommended. A reliable history of varicella should be sought at every childhood visit and persons 12 months of age or older without a history of disease should be immunized. Evidence of immunity or record of immunization should be documented in the medical record. Evidence of immunity should consist of a physician's diagnosis of varicella, a reliable history of varicella, or serologic evidence of immunity. Special emphasis should be placed on the immunization of susceptible older children before entry into middle school, because the likelihood of severe infection increases with age.

The American Academy of Pediatrics strongly encourages pediatricians to support public health officials in the development and implementation of varicella immunization requirements for child care and school entry.

In addition, the following new recommendations are presented:

1. HIV-infected and other children with altered immunity. Children with impaired humoral immunity may be immunized with varicella vaccine. However, varicella vaccine should not be administered routinely to children who have cellular immunodeficiencies including persons with leukemia,

lymphoma, other malignancies affecting the bone marrow or lymphatic systems, and congenital T-cell abnormalities. Exceptions include children with acute lymphocytic leukemia, to whom vaccine may be given through a research protocol, and certain children infected with HIV. Children infected with the human immunodeficiency virus (HIV) may be at increased risk of morbidity from varicella and herpes zoster. Limited data on immunization of HIV-infected children in the Centers for Disease Control and Prevention class I (CD4+ T-lymphocyte percentage of 25% or more) indicate that the vaccine is safe, immunogenic, and effective. Therefore, weighing potential risks and benefits, varicella vaccine should be considered for HIV-infected children in the Centers for Disease Control and Prevention class I with mild or no signs or symptoms. With the increased use of varicella vaccine and the resulting decrease in incidence of varicella in the community, exposure of immunocompromised hosts to varicella-zoster virus will decrease. As the risk of exposure decreases and more data are generated on the use of varicella vaccine in high-risk populations, the risk versus benefit of varicella immunization in HIV-infected children will need to be reassessed.

2. Postexposure immunization. Varicella vaccine may be effective for preventing or modifying varicella when given to household contacts within 3 days of the appearance of the rash in the index case. The use of varicella vaccine in susceptible children after exposure to varicella is recommended.
3. Storage and administration. The vaccine should be stored in a freezer with an average temperature of –15 degrees C (+5 degrees F) or colder; however, recent data indicate that it is acceptable to store vaccine at refrigerator temperature (2 degrees C-8 degrees C [36 degrees F-46 degrees F]) for up to 72 continuous hours before administration. Once reconstituted, the vaccine must be used within 30 minutes or discarded.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate utilization of varicella vaccine may decrease hospitalizations, serious complications, and death attributable to varicella infection. Prevention or reduction in the societal disruption associated with children missing school or child care may also result from appropriate utilization of varicella vaccine.

Effectiveness of Varicella Vaccine

Varicella vaccine has been demonstrated to be very effective. Prelicensure, controlled, clinical trials demonstrated varicella vaccine to be 70% to 90% effective for preventing varicella and more than 95% effective for preventing severe varicella. A postlicensure study of 148 children performed during an outbreak of varicella in a child care center in DeKalb County, GA, found that varicella vaccine was 86% (95% confidence interval [CI], 73%-92%) effective for preventing varicella and 100% (95% CI, 96%-100%) effective for preventing moderate to severe disease. Varicella was less severe and resulted in fewer days of absence from the day care center among immunized compared with unimmunized cases. Two more recent studies found that varicella vaccine was 86% (95% CI, 67%-94%) and 84% effective (95% CI, 60%-94%), respectively, for preventing varicella and 100% effective for preventing severe varicella. "Breakthrough" disease following exposure to wild-type varicella-zoster virus (VZV) occurs in about 1% to 4% of vaccinees per year, and the rate does not seem to increase with length of time after immunization. "Breakthrough" disease is usually of short duration and mild with fewer than 50 lesions and low-grade or no fever.

Subgroups Most Likely to Benefit:

Children infected with the human immunodeficiency virus (HIV) may be at increased risk of morbidity from varicella and herpes zoster. See the "Major Recommendations" field for a discussion of the benefits and risks of vaccination in this particular group of children.

POTENTIAL HARMS

Adverse Events

Varicella vaccine is safe; reactions are generally mild and occur with an overall frequency of approximately 5% to 35%. Approximately 20% of immunized persons will experience minor injection site reactions (e.g., pain, redness, swelling). Approximately 3% to 5% of immunized children will develop a localized rash, and an additional 3% to 5% will develop a generalized varicella-like rash. These rashes typically consist of 2 to 5 lesions and may be maculopapular rather than vesicular; lesions usually appear 5 to 26 days after immunization. However, most varicella-form rashes that occur within the first 2 weeks after varicella immunization are due to wild-type VZV. Although a temperature higher than 38.9Â°C (102Â°F) has been observed from 1 to 42 days after immunization in 15% of healthy immunized children, fever also occurs in a similar percentage of children receiving placebo and is not considered to be a significant adverse event of immunization. A temperature higher than 37.8Â°C (100Â°F) has been reported in 10% of adolescents and adults who are immunized with the vaccine. Serious adverse events, such as encephalitis, ataxia, erythema multiforme, Stevens-Johnson syndrome, pneumonia, thrombocytopenia, seizures, neuropathy, and death, have been reported rarely in temporal association with varicella vaccine. In some cases, wild-type VZV or another causal agent has been identified. In most cases, data are insufficient to determine a causal association.

Herpes Zoster After Immunization

The varicella vaccine virus has been demonstrated to cause herpes zoster in immunocompetent and immunocompromised persons within 25 to 722 days after immunization. Data from postlicensure surveillance indicate that the age-specific risk of herpes zoster seems to be lower in immunocompetent children immunized with varicella vaccine than in children who have had natural infection. A population-based study indicated that the incidence of herpes zoster after natural varicella infection among immunocompetent children younger than 20 years of age was 68 per 100,000 person-years while the reported rate of herpes zoster after varicella immunization among immunocompetent persons was approximately 2.6 per 100,000 vaccine doses distributed. However, these rates should be compared cautiously because the former rates are based on populations monitored actively for longer periods than the passive surveillance after immunization. Wild-type varicella zoster virus also has been identified in persons with herpes zoster after immunization, indicating that herpes zoster in immunized persons also may result from antecedent natural varicella infection.

Transmission of Vaccine-Associated Virus

Experience during the past 4 years with more than 14 million doses of varicella vaccine distributed in the United States indicates that vaccine-associated virus transmission to contacts is extremely rare (only 3 well-documented cases to date) and occurs only if the immunized person develops a rash.

Subgroups Most Likely to be Harmed:

Varicella vaccine should not be administered routinely to children who have cellular immunodeficiencies including persons with leukemia, lymphoma, other malignancies affecting the bone marrow or lymphatic systems, and congenital T-cell abnormalities. See the "Major Recommendations" field.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics. Committee on Infectious Diseases. Varicella vaccine update. Pediatrics 2000 Jan;105(1 Pt 1):136-41. [34 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Jan

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Infectious Diseases

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. This guideline updates/reaffirms a previously issued guideline (Recommendations for the use of live attenuated varicella vaccine. Pediatrics 1995;95:791-6).

AAP Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. Until the Board of Directors approves a revision or reaffirmation, or retires a statement, the current policy remains in effect.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site.

Print copies: Available from AAP, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 20, 2001. The information was verified by the guideline developer as of December 5, 2001.

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